K112540

510(K) SUMMARY

FEB - 3 2012

Submitter:

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Device Information:

Device Name: S-MiNi Implant System

Classification Name: Implant, Endosseous, Root-Form

Common Nmae: Endosseous Dental Implant

Classification: Class II

Product Code: DZE

Regulation number: 21 CFR 872.3640

Date of Submission: 8/25/2011

Device Description

The S-MiNi System has two types, cement type and ball type.

The S-MiNi Implant System is a one-piece endosseous dental implant which is a combination of implant and abutment sections. The implant is a made of Unalloyed Titanium (G4). The surface was granted with microscopic roughness through the RBM surface treatment.

Indication for use

The S-MiNi Implant System is divided into two types:

- **Cement Type**

The Cement type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients.

- **Ball Type**

The Ball type is designed for use in dental implant surgery. Ball type is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures. Ball type implants are for temporary use, only.

Performance Standards

Bench tests including visual, size, package, package seal efficacy, compressive load, and retention force testing, were performed successfully.

Predicate devices

- Cement Type

MS Implant(Narrow Reidge) by OSSTEM Implant., Ltd, K080594

Intermezzo ™ Implant System by Megagen Co., ltd. K051018

- Ball Type

MS Implant (Denture) by OSSTEM Implant., Ltd., K072959

DIO Protem Implant System by DIO Department, DSI, Inc., K080126

Comparison Chart

Cement type			
product Name	S-MiNi Implant	MS Implant	Intermzzo ™Implant System
510(k)	N/A	K080594	K051018
Manufacturer	neobiotech Co., Ltd	OSSTEM Implant., Ltd	MegaGen Co., Ltd
Shape			
Intended use	Identical to the predicate	The MS System is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous.	The Intermezzo TM Implant Systems are intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.
Comparition of Matertial	Titanium Grade 4 of ASTM F 67	Ti-6AL-4V ELI Alloy of ASTM F 136	CP Titanium G3

Device design	Dia(Ø)	2.0/2.5/3.0/3.5	2.5/3.0	1.6/2.0/2.5/3.1
	Cuff(mm)	2	2.5	-
	Post(mm)	10	7	-
	Lengrh(mm)	7.0/8.5/10.0/11.5/ 13.0/15.0	10.0/13.0/15.0	7.0/8.5/10.0/11.5/13.0/ 15.0
Surface Treatment		RBM	RBM	RBM
Biocompatibility		Yes	Yes	Yes
Sterilization		Gamma Sterilization	Gamma Sterilization	Gamma Sterilization

Ball type				
product Name		S-MiNi Implant	MS Implant (Denture)	DIO Protem Implant system
510(k)		N/A	K072959	K080126
Manufacturer		neobiotech Co., Ltd	OSSTEM Implant., Ltd	MegaGen Co., Ltd
Shape				
Intended use		Identical to the predicate	The MS System (Denture) is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. MS System (Denture) is intended for single use only.	The DIO Protem Implant Systems are intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.
Comparition of Matertial		Titanium Grade 4 of ASTM F 67	Ti-6AL-4V ELI Alloy of ASTM F 136	Ti-6AL-4V ELI Alloy of ASTM F 136
Device design	Dia(Ø)	2.0/2.5/3.0/3.5	2.5/3.0	2.0/2.5
	Cuff(mm)	3.0/4.0	2.0/4.0	2.0/4.0
	Lengrh(mm)	7.0/8.5/10.0/11.5/ 13.0/15.0	10.0/13.0/15.0	8.0/10.0/12.0/14.0
Surface Treatment		RBM	RBM	RBM
Biocompatibility		Yes	Yes	Yes
Sterilization		Gamma Sterilization	Gamma Sterilization	Gamma Sterilization

Summary of Substantial Equivalence Comparison

The Cement type of S-MiNi Implant system is the same device characteristics as the predicate devices, The MS System(Narrow Ridge) and Intermezzo ™ Implant System; intended use, material, design and use concept are similar.

The Ball type of S-MiNi Implant system is the same device characteristics as the predicate devices, The MS System(Denture) and DIO Protem Implant System; intended use, design and use concept are similar.

Based on the comparison of intended use and technical features, S-MiNi Implant System are substantially equivalent to the predicate device.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification neobiotech Co., Ltd. concludes that the S-MiNi Implant system is substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neobiotech Company, Limited
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FEB - 3 2012

Re: K112540
Trade/Device Name: S-MiNi Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 3, 2012
Received: February 2, 2012

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K112540

Device Name: S-MiNi Implant System

Indications for Use:

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- **Cement Type**

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Prescription Use _____X_____ **AND/OR** **OverThe-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number: K112540